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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,030	12/28/2001	Scott Powers	018781-006810US	2471

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/041,030

Applicant(s)

POWERS ET AL.

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 8-10, 12, 13 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 38-41 is/are allowed.
- 6) ☐ Claim(s) 8-10, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/10/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

1. The Amendment filed May 6, 2005 in response to the Office Action of January 12, 2005 is acknowledged and has been entered. Previously pending claims 1-7, 11 have been cancelled. Although Applicant states that claims 14-27 have also been canceled, a review of the listing of the claims reveals that claims 14-37 have in fact been cancelled and therefore it is assumed for examination purposes that the statement in the response drawn to claims 14-27 is an inadvertent typographical error and that in fact it is claims 14-37 that have been canceled. Claims 8-10 and 12 have been amended and new claims 38-41 have been added. Claims 8-10, 12-13, 38-41 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

Claim Rejections - 35 USC 112

4. Claims 8-9, 12-13 remain rejected under 35 USC 112, first paragraph essentially for the reasons previously set forth in the action mailed January 12, 2005, Section 7, pages 2-7.

Applicant argues that although Examiner contends that Applicants have not described structural features common to the members of the genus, Applicants have taught that other Pellino 2 polypeptides, i.e. mouse are known in the art and points to page 5, lines 19-23. Such polypeptides share a high degree of sequence identity as evidenced by the sequence alignment provided in Appendix A. Thus there is no reason to believe that one of skill would not understand what a Pellino 2 polypeptide that has 95% identity to the reference sequence is.

The argument has been considered but has not been found persuasive because a review of page 5, lines 19-23 reveals teaching drawn to a mouse

homolog of human Pellino 2 mRNA, mouse Pellino 2 mRNA Accession No. AF302504, however the citation does not reveal the identity of the polypeptide encoded by the mouse Pellino 2 mRNA to SEQ ID NO:4, does not reveal that the gene encoding the polypeptide encoded by Accession No. AF302504 is amplified in an epithelial cancer. Although one would know what a polypeptide with 95% identity to SEQ ID NO:4 consists of, the teaching of the mouse mRNA does not give an adequate written description of the genus because no structural features commonly possessed by the members of the genus (that is the genus of polypeptides encoded by a gene that is amplified in epithelial cancer cells) that distinguish them from others have been identified. Therefore, one skilled in the art cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus

Applicant states that Applicant must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. The claims recite detection of a gene encoding a Pellino 2 polypeptide that has at least 95% to a reference sequence, which is intended to cover potential human allelic variants of SEQ ID NO:4, known or unknown. The Examiner provides no reasoning or evidence that the sequences of such alleles must be explicitly provided in order for one of skill to understand that Applicants had possession of the invention, that is that the discovery that Pellino 2 is increased in copy number in cancer. The argument has been considered but has not been found persuasive. Applicant admits on the record that the limitation drawn to 95% identity is particularly made in order to provide patent protection for "potential" amplified human allelic variants of SEQ ID NO:4, known or unknown. Clearly Applicant does not have possession of

amplified human allelic variants which are unknown and does not have possession of a method of detecting epithelial cancer cells by detecting amplification of unknown human allelic variants in a sample. Further, Applicant discloses only a single human polynucleotide which is amplified in epithelial cancer cells.

Although Applicant states that the limitation drawn to 95% identity is particularly made in order to provide patent protection for "potential" human allelic variants of SEQ ID NO:4, known or unknown, it appears that Applicant is in possession of only one polynucleotide that is known to be amplified in epithelial cancers. This is not sufficient to meet the requirements of either *Enzo* or *Lilly* for the reasons previously set forth.

Applicant describes the methods and discloses the usefulness of Pellino 2 for diagnosis and argues that the detection of Pellino 2 can also be used to understand that applicants had possession of the invention, that is the discovery that Pellino 2 is increased in copy number in cancer. The argument has been considered but has not been found persuasive because the argument is not relevant to the instant rejection. Although the specification exemplifies the association of increased copy number of the Pellino 2 gene which encodes SEQ ID NO:4 in both colon and ovarian tumors, this does not provide a written description for the broadly claimed methods and is not sufficient to meet the requirements of either *Enzo* or *Lilly* for the reasons previously set forth.

Applicant argues that (a) the Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an Applicant's disclosure a description of the invention defined by the claims and cites MPEP 2163.04, (b) the Examiner provides no evidence that naturally occurring allelic variants at the Pellino 2 locus would not also undergo an

increase in copy number in cancer, (c) Examiner provides no reasoning that one of skill would require that the sequences of allelic variants be explicitly provided in order to recognize that applicants invented what is claimed, detection of epithelial cancer cells by detecting an increase in copy number of the Pellino 2 locus, (d) Examiner fails to provide evidence that indicates that the ordinary artisan could not predict the operability in the invention of any species other than the one that is specifically disclosed, (e) the claims are adequately described by providing the specific sequence of only SEQ ID NO:4.

The arguments have been considered but have not been found persuasive because (a') Examiner has presented a reasonable basis to challenge the adequacy of the written description. The basis is case-law specifically drawn to the biotechnology nucleic acid arts. Examiner has carefully analyzed the instant fact pattern and compared it to the fact patterns of both *Lilly* and *Enzo* and it is very clear, for the reasons set forth previously, that the instant application does not meet the requirements of the written description provision of 35 USC 112, first paragraph for the reasons of record, (b')(d') the argument is not relevant to the instant rejection, the rejection is not an enablement rejection but rather is drawn to the written description requirements of 35 USC 112, first paragraph, (c') the argument is not relevant because Applicant is arguing limitations not recited in the claims as currently constituted, the claims are not drawn to detection of epithelial cancer cells by detecting an increase in copy number of the Pellino 2 locus, but rather are drawn to said method by detecting an increase in copy number of a gene encoding a Pellino 2 polypeptide comprising at least 95% amino acid sequence identity to SEQ ID NO:4, (e') the claims are not adequately described by providing the specific sequence of only SEQ ID NO:4 for the reasons of record.

Applicant argues that the MPEP explicitly states that description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces and cites MPEP 2163(II)(A)(3)(ii) which passage provides an example from the molecular biology arts where, if an applicant discloses an amino acid sequence, it is unnecessary to provide an explicit disclosure of nucleic acid that encodes the amino acid sequence wherein the case law is drawn to *In re Bell*. Applicant states that given the above, Applicants are not required to elaborate degenerate variants of SEQ ID NO:3 that encode SEQ ID NO:4 to provide adequate written descriptive support. The argument has been considered but has not been found persuasive because Applicant is once again arguing limitations not recited in the claims as currently constituted. In particular, the claims are not drawn to degenerate sequences encoding SEQ ID NO:4, but rather are drawn to methods of detecting epithelial cancer by detecting increased copy number of a gene encoding a Pellino 2 polypeptide comprising at least 95% identity to SEQ ID NO:4.

The arguments have been considered but have not been found persuasive and the rejection is maintained.

New Grounds of Objection

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.8821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reasons(s) set forth on the attached Notice to Comply with Requirements for Patent Applications Containing Nucleotide

Sequence And/Or Amino Acid Sequence Disclosures. In particular, pages 54 and 55 contain nucleic acid sequences that are not identified by sequence identifiers. Applicant is given the period for reply to the instant action within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821 (g). In no case may an applicant extend the period for response beyond the SIX MONTH statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Examiner has made an effort to identify these informalities but applicant must carefully review the specification to identify and indicate where these informalities may be found. Appropriate correction is required.

New Grounds of Rejection

Claim Rejections - 35 USC 112

6. Claims 8-10, 12-13 are rejected under 35 USC 112, first paragraph as the specification does not contain a written description of the claimed invention. The limitation of a method of detecting epithelial cancer cells in a biological sample comprising detecting an increase in copy number of a gene encoding a Pellino 2 polypeptide comprising at least 95% amino acid identity to SEQ ID NO:4 recited in claim 8 from which claims 9-10, 12-13 depend has no clear support in the specification and the claims as originally filed. In the response filed May 6, 2005 Applicant points to page 7, lines 20-26 to establish support for the newly claimed limitation. However, a review of the cited support reveals support for "Pellino 2 nucleic acid and polypeptide polymorphic variants, alleles, mutants, and interspecies homologs that:(1) have an amino acid sequence that has greater than about 60% amino acid sequence identity, 65%, 70%, 75%, 80%, 85%, 90%,"

preferably 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98% or 99% or greater amino acid sequence identity, preferably over a region of 25 over a region of at least about 50, 100, 200, 500, 1000, or more amino acids, toa Pellino 2 sequence of SEQ ID NO:4". The suggested support has been considered but has not been found persuasive because although the support refers to a nucleotide sequence which encodes a polypeptide with greater than about 95% identity to a Pellino 2 sequence of SEQ ID NO:4, the cited support is not drawn to the newly added limitation of a method of detecting epithelial cancer cells by detecting an increase in copy number of a gene encoding a Pellino 2 polypeptide comprising at least 95% amino acid identity to SEQ ID NO:4. The subject matter claimed in claims 8-10, 12-13 broadens the scope of the invention as originally disclosed in the specification.

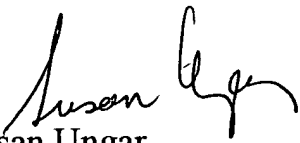
7. Claims 38-41 appear to be free of the art and allowable.
8. Applicant's amendment necessitated the new grounds of rejection. Thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.


Susan Ungar
Primary Patent Examiner
July 21, 2005